

314-6

2/28/2014

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 28 2014

Mr. Matthew Feinberg
Authorized Agent for Novozymes BioAg, Inc.
Exponent, Inc.
1150 Connecticut Avenue NW, Suite 1100
Washington, D.C. 20036

Re: Novozymes BioAg, Inc.; NoFly™ WP
EPA Registration No. 73314-6
Minor Label and Formulation ("Fast Track") Amendment
Submissions Dated 07/18/2013, 02/14/2014, and 02/25/2014
Decision No. 481150

Dear Mr. Feinberg:

The U.S. Environmental Protection Agency (EPA) reviewed your request to amend the subject product registration, which included the following changes to the product label:

- 1) Correction of minor formatting inconsistencies and typographical errors.
- 2) Revision of the overall structure of the NoFly™ WP labeling, so it now includes text for labels securely attached to NoFly™ WP containers and text for pull-off booklets located on the front of NoFly™ WP containers.
- 3) Modification of language that explains the purpose of text and/or images found within curly and square brackets (i.e., comments to label reviewers or optional label items).
- 4) Modification of the referral statement for the Precautionary Statements, First Aid, Directions for Use, and Warranty.
- 5) Addition of First Aid statements for eye and oral exposure (Chapter 7, Section III(F) of the EPA's Label Review Manual – Revised July 2012).

		CONCURRENCES			
IBOL	7511P	7511P	7511P		
NAME	KAUSCH	Corpus	Ureni		
	02/25/2014	2/26/14	2/28/14		

Form 1320-1A (1/90)

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- 6) Addition of Hot Line Number information to the First Aid box (Chapter 7, Sections III(F)(9) and III(F)(10) of the EPA's Label Review Manual – Revised July 2012).
- 7) Replacement of "EPA Est. No.:" with "EPA Est. No. 73314-TX-001."
- 8) Replacement of "Net Contents" with "Net Weight" as NoFly™ WP is a solid (Chapter 17, Section III of the EPA's Label Review Manual – Revised November 2012) and addition of an actual container size (in both U.S. and metric units) after "Net Weight."
- 9) Modification of the registrant's name and the registrant's contact information (e.g., street address) to reflect a recent company transfer.
- 10) Addition of several comments for label reviewers in curly brackets (e.g., "Batch code to be inserted") and optional label items in square brackets (e.g., "NOVOZYMES RETHINK TOMORROW").
- 11) Rearrangement of certain statements in the Hazards to Humans and Domestic Animals section to ensure that these statements are organized so that the routes of exposure of most concern, as supported by toxicity category classifications, are listed first (Chapter 7, Section III(D)(3) of the EPA's Label Review Manual – Revised July 2012).
- 12) Addition of the following statement to the Hazards to Humans and Domestic Animals section (Chapter 7, Section III(D) of the EPA's Label Review Manual – Revised July 2012):
 "Causes moderate eye irritation."
- 13) Modification of the following statements in the Hazards to Humans and Domestic Animals section (Chapter 7, Section III(D) of the EPA's Label Review Manual – Revised July 2012) (changes emphasized):
 "Avoid breathing dust or spray mist."
 "Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet."
 "When handling this product, wear protective eyewear and waterproof gloves."

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- 14) Modification of the following statements in the Personal Protective Equipment section to align with information presented in Chapter 10, Sections VI(A) and VI(B) of the EPA’s Label Review Manual (Revised September 2013) and with standard text found on other microbial pesticide product labels (changes emphasized):

“Personal Protective Equipment (PPE): Applicators and other handlers must wear protective eyewear, long-sleeved shirt, long pants, waterproof gloves, shoes, and socks. Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Follow the manufacturer’s instructions for cleaning/maintaining PPE. If no such instructions are available for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

- 15) Removal of the following advisory statement from the User Safety Recommendations box because it is already present in the Hazards to Humans and Domestic Animals section as a mandatory statement:

“Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.”

- 16) Modification of the statements in the User Safety Recommendations box to align with information presented in Chapter 10, Section VI(D) of the EPA’s Label Review Manual (Revised September 2013).

- 17) Modification of the statements in the Environmental Hazards section to align with information presented in Chapter 8 of the EPA’s Label Review Manual (Revised September 2012).

- 18) Modification of the following statement in the Directions for Use (Chapter 10, Section VII(A) of the EPA’s Label Review Manual – Revised September 2013)(changes emphasized):

“For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

- 19) Revision of the restricted-entry interval (REI) from 4 hours to 12 hours, given that NoFly™ WP does not qualify for a reduced REI because its active ingredient is a dermal sensitizer (Pesticide Registration Notice 95-3).

- 20) Addition of protective eyewear to the listing of early-entry PPE in the Agricultural Use Requirements box to align with information presented in Chapter 10, Section VII(C)(3) of the EPA’s Label Review Manual (Revised September 2013).

- 21) Modification or adjustment of several statements in the Directions for Use for clarification purposes (e.g., arrangement of the Preparation, Mixing, and Application Instructions).

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- 22) Reduction of one of the specified application rates (i.e., from 1 – 4 pounds per acre to 1 – 2 pounds per acre), so that none of the specified NoFly™ WP application rates exceed its container size of 2 pounds (Chapter 17, Section IV(C) of the EPA’s Label Review Manual – Revised November 2012).
- 23) Adjustment of text in the Storage and Disposal box to align with information presented in Chapter 13 of the EPA’s Label Review Manual (Revised July 2013) and to account for the intended packaging of the product (i.e., 2-pound bags).
- 24) Modification of the Warranty section to reflect a recent company transfer.

Additionally, you updated the CSF on file for NoFly™ WP. There is now only one valid CSF for this product registration: a basic formulation dated February 10, 2014. All previously accepted NoFly™ WP CSFs have been superseded by the aforementioned CSF.

All the changes referred to above, submitted in connection with registration under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), are acceptable provided that you submit two (2) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for further description of final printed labeling.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. If you have any questions regarding this letter, please contact Ms. Jeannine Kausch by telephone (703-347-8920) or email (*kausch.jeannine@epa.gov*).

A stamped, accepted copy of the label is enclosed for your records.

Sincerely,

Kimberly Nesci Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures (2):

- NoFly™ WP Stamped, Accepted Label
- A-79 Enclosure

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Note to reviewer:

{ } – Denotes comments to the reviewer, and [] – Denotes optional statements and/or images.

{This label reflects the unit package labeling and will be presented as a booklet on the front of the product container.}

NOFLY™ WP

ACCEPTED

Wettable Powder Mycoinsecticide

FEB 28 2014

For Greenhouse Use Only

**Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 73314-6**

ACTIVE INGREDIENT:

<i>Paecilomyces fumosoroseus</i> strain FE 9901	18.0%
Other Ingredients	82.0%
Total	100.0%

*Contains a minimum of 2x10⁸ colony forming units of *Paecilomyces fumosoroseus* strain FE 9901 per gram (Dry Weight Basis)

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

**See inside this booklet for [additional Precautionary Statements, and] complete
First Aid, Directions for Use, and the Warranty.**

FIRST AID	
If on skin or clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 – 20 minutes. • Call a poison control center or doctor for treatment advice.
If inhaled:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
If in eyes:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice
If swallowed:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific Time (PT), seven days a week. During other times, call your local poison control center at 1-800-222-1222.</p>	

EPA Reg. No.: 73314-6
EPA Est. No.: 73314-TX-001
Net Weight: [2lb][907g]

Novozymes BioAg, Inc.
13100 W. Lisbon Road, Suite 600
Brookfield, WI 53005
800-245-4104

[NOVOZYMES RETHINK TOMORROW][LOGO]
[Made in the][USA]

Batch code: {Batch code to be inserted}
Best If Used By: 3 months from manufacturing date
{Label or Container will bear date of manufacture}

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PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: Caution. Harmful if absorbed through the skin, inhaled, or swallowed. Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with skin, eyes or clothing. Avoid breathing dust or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. When handling this product, wear protective eyewear and waterproof gloves.

Personal Protective Equipment (PPE): Applicators and other handlers must wear protective eyewear, long-sleeved shirt, long pants, waterproof gloves, shoes, and socks. Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions are available for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY REQUIREMENTS

Users should:
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Environmental Hazards: Do not contaminate water when disposing of equipment washwaters or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **For greenhouse use only. Not for use on food crops.** Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of twelve (12) hours.

PPE required for early entry to treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water) is: coveralls, waterproof gloves, shoes plus socks, and protective eyewear.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of the product that are not within the scope of the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of treated areas until sprays have dried or dusts have settled.

For use in controlling Whitefly, Aphids, Thrips, Psyllids, Mealybugs, Leaf Hoppers, Plant Bugs, Weevils, Grasshoppers, Mormon Crickets, Locust, Beetles and Fungus Gnats on non-food crops and ornamentals in greenhouses.

NOFLY™ WP contains live spores of the naturally occurring fungus, *Paecilomyces fumosoroseus* strain FE 9901, and food grade inert (other) ingredients. The spores are alive and may be harmed by storage at high temperatures (>8°C or >46.4 °F) or contact with water for more than 24 hours.

NOFLY™ WP can be applied using conventional spraying equipment. Use of manual sprayers is highly recommended, with a minimum working pressure of 40 psi. NOFLY™ WP works best in a pest management program designed to keep insect populations below levels that damage non-food crops and ornamentals. Typically, it takes 3-7 days for an infected insect to die and 7-10 days after the first spray to see a reduction in an insect population. Application rates, spray frequency, spray coverage and insect numbers affect the speed at which insect populations are reduced. Frequent scouting for insects in non-food crops and ornamentals is recommended. NOFLY™ WP is most effective when used at the first appearance of insects in non-food crops and ornamentals, before high insect populations develop.

NOFLY™ WP may be combined with chemical insecticides for rapid knockdown of damaging insect populations or large numbers of insects moving into non-food crops and ornamentals. NOFLY™ WP can also be used in combination with fertilizers and micronutrients. If tank mixes are desired, observe the most restrictive directions, precautions, and limitations on labeling of all products used. Do not exceed label application rates. This product cannot be mixed with any product containing a label prohibition against such mixing. The application of fungicides is not compatible with NOFLY™ WP. A week is the minimum period allowed between treatment with fungicides and application of NOFLY™ WP. Applications of any other pesticides must be carefully studied, taking into account that the active substance of NOFLY™ WP consists of a microorganism and any substance that could affect its viability must be avoided.

Application Sites	Application Timing	Application Rates
Non-food crops and ornamentals in greenhouses	At any stage of the crop. Applications must be done at the first sign of insect larvae.	1 - 2 lbs /acre 4 oz–16 oz NOFLY™ WP per 11,000 sq ft of greenhouse applied at a minimum of 0.1% active ingredient (i.e., 28 oz NOFLY™ WP per 100 gallons of water)

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Preparation, Mixing, and Application Instructions

1. If refrigerated, remove NOFLY™ WP from refrigeration unit and store at room temperature for at least 3 days prior to application.
2. Dissolve the contents of bag in an appropriate volume of water and mix with a stirring device to get a homogeneous suspension. Apply immediately using conventional spraying equipment. A minimum pressure of 40 psi is recommended for the applications.
3. Apply 26 gallons of prepared solution per 11,000 sq ft of greenhouse for small non-food crops and ornamentals and up to 100 gallons of prepared solution per 11,000 sq ft of greenhouse for full grown non-food crops and ornamentals.
4. First applications should be done at the first symptoms of the presence of larvae or eggs on the leaves. Repeat applications 2–3 times at 15-day intervals or shorter (every 5–8 days) in the case of heavy infestations.
5. Apply enough quantity of prepared solution (NOFLY™ WP + water) for a good coverage on the plants, trying to reach the lower-sides of the leaves.
6. Applications should be conducted during low solar radiation (late afternoon or early night) when there is high relative humidity inside the greenhouse and the temperature is below 30°C (86°F).
7. NOFLY™ WP supports the action of natural predators of whitefly and other pests; therefore, it is ideal for IPM programs.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage: NOFLY™ WP should be stored at a refrigerated temperature (4°C - 8°C or 39°F - 46°F). Under these conditions, the product is physico-chemically stable for at least 3 months, although viability may decrease with a factor 10.

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then, offer for recycling if available, dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY

The Directions for Use of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and must be followed carefully. Novozymes BioAg, Inc. warrants that at the time of the first sale of this product it conforms to the chemical description on the label and when used according to the label directions under normal growing conditions is reasonably fit for the purposes referred to above. Buyers/Users of this product assume full risk for any use contrary to the specified directions. If this product does not perform as warranted above and to the extent consistent with applicable law, customer's sole remedy for breach of warranty shall be replacement of the product or refund of the purchase price paid, at the option of Novozymes BioAg, Inc.

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EXCEPT AS PROVIDED ELSEWHERE IN WRITING CONTAINING AN EXPRESSED REFERENCE TO THIS WARRANTY AND LIMITATION OF DAMAGES, SELLER MAKES NO OTHER EXPRESSED OR IMPLIED WARRANTY OR GUARANTEE TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, INCLUDING ANY OTHER EXPRESSED OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.

{Note: The following information will affixed to the unit package}

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NOFLY™ WP

Wettable Powder Mycoinsecticide

For Greenhouse Use Only

ACTIVE INGREDIENT:

<i>Paecilomyces fumosoroseus</i> strain FE 9901	18.0%
Other Ingredients	82.0%
Total	100.0%

*Contains a minimum of 2x10⁹ colony forming units of *Paecilomyces fumosoroseus* strain FE 9901 per gram (Dry Weight Basis)

KEEP OUT OF REACH OF CHILDREN CAUTION

See attached booklet for [additional Precautionary Statements, and] complete First Aid, Directions for Use, and Warranty.

EPA Reg. No.: 73314-6
EPA Est. No.: 73314-TX-001
Net Weight: [2lb][907g]

Novozymes BioAg, Inc.
13100 W. Lisbon Road, Suite 600
Brookfield, WI 53005
800-245-4104

[NOVOZYMES RETHINK TOMORROW][LOGO]
[Made in the][USA]

Batch code: {Batch code to be inserted}
Best If Used By: 3 months from manufacturing date
{Label or Container will bear date of manufacture}

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: Caution. Harmful if absorbed through the skin, inhaled, or swallowed. Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with skin, eyes or clothing. Avoid breathing dust or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. When handling this product, wear protective eyewear and waterproof gloves.

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Environmental Hazards: Do not contaminate water when disposing of equipment, washwaters or rinsate.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage: NOFLY™ WP should be stored at a refrigerated temperature (4°C - 8°C or 39°F - 46°F). Under these conditions, the product is physico-chemically stable for at least 3 months, although viability may decrease with a factor 10.

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then, offer for recycling if available, dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

{Note: These are optional claims and graphics that can be found in the booklet and/or on the affixed label.}

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OPTIONAL LABEL CLAIMS

- For Use in Organic Production
- For Use in Organic Gardening
- For Organic Production
- For Organic Gardening
- NOP logo

